K061580

JUL 28 2006

510(k) SUMMARY

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17405-0872

CONTACT:	Helen Lewis
DATE PREPARED:	June 2, 2006
TRADE OR PROPRIETARY NAME:	ECLIPSE® WAX REMOVER
CLASSIFICATION NAME:	Denture relining, repairing, or rebasing resin, 872.3760
PREDICATE DEVICES:	Trubyte® Denture Base Resin System, K011560

DEVICE DESCRIPTION:

The ECLIPSE® WAX REMOVER is an accessory to the Trubyte® Denture Base Resin System (Eclipse® Prosthetic Resin System). It facilitates the effective removal of wax from cured Eclipse® resin substructures and promotes adhesion to other acrylic resins.

INTENDED USE:

The ECLIPSE® WAX REMOVER is used as an accessory to Eclipse® Prosthetic Resin System to remove wax and aid in adhesion to other acrylic resins in (1) the fabrication of dentures, appliances, and prostheses; (2) repair of dentures, appliances, and prostheses; and (3) relining of denture surfaces.

TECHNOLOGICAL CHARACTERISTICS:

All of the components found in ECLIPSE® WAX REMOVER have been used in legally marketed devices and/or were found safe for dental use. ECLIPSE® WAX REMOVER has been evaluated and passed biocompatibility testing for cytotoxicity.

We believe that the prior use of the components of ECLIPSE® WAX REMOVER in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of the ECLIPSE® WAX REMOVER for the indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2006

DENTSPLY International, Incorporated
Ms. Helen Lewis
Director of Corporate Compliance & Regulatory Affairs
Dentsply Prosthetics
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K061580
Trade/Device Name: ECLIPSE® WAX REMOVER
Regulation Number: 872.3760
Regulation Name: Denture Relining, Repairing or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: June 2, 2006
Received: June 7, 2006

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K061580

Device Name: ECLIPSE® WAX REMOVER

Indications for Use:

The ECLIPSE® WAX REMOVER is used as an accessory to Eclipse® Prosthetic Resin System to remove wax and aid in adhesion to other acrylic resins in (1) the fabrication of dentures, appliances, and prostheses; (2) repair of dentures, appliances, and prostheses; and (3) relining of denture surfaces.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Beck DDS for Dr. Susan Runner

(Div)
of Anesthesiology, General Hosp
Control, Dental Devices

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